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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,367	10/22/2003	Mathis L. Muller	2119-4280	2297
27123	7590	12/20/2005	EXAMINER	
MORGAN & FINNEGAN, L.L.P. 3 WORLD FINANCIAL CENTER NEW YORK, NY 10281-2101			IBRAHIM, MEDINA AHMED	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/692,367	Applicant(s) MULLER ET AL.	
	Examiner Medina A. Ibrahim	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 27-55 is/are pending in the application.
- 4a) Of the above claim(s) 4-6, 35-37, 44-46 and 53-55 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7-13, 27-30, 38-40 and 47-49 is/are allowed.
- 6) ☒ Claim(s) 1-3, 14-16, 31-34, 41-43 and 50-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 09/19/05 in reply to the Office action of 06/17/05 has been entered. Claims 1-16 and 27-55 are pending. Claims 4-6, 35-37, 44-46, and 53-55 are withdrawn from consideration as being directed to the non-elected invention. Claims 1-3, 7-16, 27-34, 38-43, and 47-52 are under examination. Claims 1, 7, 10, 14, 27, 31, 38, 41, 47, 50 are amended.

All previous objections and rejections not set forth below have been withdrawn in view of Applicant's amendment and/or upon further consideration.

Claim Rejections - 35 USC § 112

Claims 1-3, 14-16, 31-34, 41-43, and 50-52, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated nucleic acid comprising SEQ ID NO: 11 encoding SEQ ID NO: 12 having improved chitinase activity as compared to the wild-type maize chitinase of SEQ ID NO: 1, a vector comprising said nucleic acid, does not reasonably provide enablement for an isolated nucleic acid from any source encoding a chitinase having at least 91% sequence identity to SEQ ID NO: 12, a polynucleotide sequence that hybridizes to SEQ ID NO: 11 and that does not encode SEQ ID NO: 1, 2, 17, 18, 19, or 20 SEQ ID NO: 11, and wherein the polypeptide exhibits a chitinase activity of at least 20% or 200% of the maize chitinase of SEQ ID NO: 1, a vector comprising said polynucleotide, a plant comprising said nucleic acid, and a method of enhancing fungus resistance with said

Art Unit: 1638

polynucleotide . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record as set forth in the last Office action of 06/17/05. Applicant's arguments filed 09/19/05 have been considered but are deemed persuasive.

Applicant argues that the claims are drawn to nucleic acids having specific structural property, namely, nucleic acids encoding polypeptides having at least 91% sequence identity to SEQ ID NO: 12, and require the functional limitation that it encode a polypeptide having chitinase activity. Applicant also argues that methods of determining nucleic acids having percent of sequence identity and assays for testing and measuring chitinase activity, i.e, ability to inhibit fungal growth, are disclosed in the specification and are known in the prior art. Applicant contends that expression of nucleic acids in a transgenic plant and production transgenic plants are well known. Applicant, therefore, asserts that one of ordinary skill in the art can make and use the invention as claimed, without undue experimentation (response, pp. 9-10).

These are not persuasive because the arguments are not commensurate in scope of the claims. Claims drawn to nucleic acid encoding a chitinase polypeptide having at least 91% sequence identity to SEQ ID NO: 12, wherein the chitinase polypeptide exhibits chitinase activity of at least 20% or 200% of the chitinase activity of SEQ ID NO: 1, and nucleic acids that hybridize to SEQ ID NO: 11, with the proviso that polynucleotide does not encode SEQ ID NO: 1, 2, 17, 18, 19 or 20, and wherein the chitinase polypeptide exhibits chitinase activity of at least 20% or 200% of the chitinase

Art Unit: 1638

activity of SEQ ID NO: 1 are not supported by an enabling disclosure taking into account the in re wands factors disclosed in the last Office action. While the claims recite nucleic acids with specific structural and functional properties, the claims are not limited to nucleic acids with said specific structural and functional properties but also require chitinase activity of at least 20% and 200% of SEQ ID NO: 1 and having antifungal and anti-nematode activity upon expression in a transgenic plant. Applicant has not taught the regions of the full-length SEQ ID NO: 11-12 that are required for improved chitinase activity that is at least 20% and 200% of the chitinase activity of SEQ ID NO: 1.

Applicant also argues that nucleic acids encoding chitinase polypeptides having at least 91% identity to SEQ ID NO: 12 and having the activity as recited in the claims are disclosed in the specification. However, none of the nucleic acids disclosed in the specification was expressed in a transgenic plant, and therefore, the functional property of the nucleic acids when expressed in a transgenic plant is unpredictable. The state of the art is that transformation of a plant with a gene is routine. However, transformation of a plant with a gene for specific phenotype is highly unpredictable. Furthermore, Applicant has not taught that a single variant that hybridizes to SEQ ID NO: 11 and capable of providing protection against plant fungal and nematode pathogens.

While patent application need not teach, and preferably omits what is well known in the art, the Federal Circuit has cautioned against over-reliance on the rule. See *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997): "[T]hat general, oft-repeated statement is merely a rule of

Art Unit: 1638

supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement". The *Genentech* court also held that [w]hile every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention". *Id.* In this case, as in *Genentech*, the specification does not provide the "reasonable detailto enable members of the public to understand and carry out the invention".

Cornelissen et al (US 5, 670, 706) discuss the fungal resistance activity by hydrolytic enzymes as follows: "(L)ittle is known about the effect of hydrolytic enzymes on fungi in the biotrope, i.e., in the soil or on plant leaves, and although some of these enzymes are putative candidates for a role in fungal resistance, evidently, not all chitinases have activity against living fungi" (column 3, lines 22-26). In column 5, lines 29-34, the cited reference states "it seems at least doubtful that any chitinase can confer broad range protection of plants against phytopathogenic fungi. Generally, it is even questionable if chitinases by themselves are capable of providing sufficient protection against a broad range of plant pathogenic fungi".

In addition, the working examples disclosed in the specification is limited to an in vitro use of SEQ ID NO: 11 against specific fungus and nematode pathogens, and no

Art Unit: 1638

transgenic plant with resistance against fungus or nematode as a result of expressing exemplified or non-exemplified nucleic acids has been disclosed.

Therefore, given the lack of guidance in the specification, lack of working example regarding transgenic plants, the state of the prior art, the nature of the invention, and the unpredictability as discussed above, the claimed invention is not enabled throughout the broad scope as stated in the last Office action.

Remarks

Claims 1-3, 7-16, 27-34, 38-43, and 47-52 are deemed free of the prior art of record.

Claims 7-13, 27-30, 38-40, and 47-49 are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1638

Contact information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Mai

12/12/05

MEDINA A. IBRAHIM
PATENT EXAMINER

